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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,814	08/21/2003	Lucien A. Couvillon JR.	S13.12-0146	7877

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EXAMINER

DEMILLE, DANTON D

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/645,814

Applicant(s)

COUVILLON, LUCIEN A.

Examiner

Danton DeMille

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

**Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown III in view of Shabty et al., Madden et al. and Hegde et al.**

Brown teaches applicant's system for exerting a compressive force on an exterior treatment portion of a user's body comprising a covering member for covering the treatment portion and an electroactive polymer (EAP) actuator operably connected to the covering for compressing the treatment portion of the user's body. Brown gives examples of the polymers that re useful in the present invention however, Brown's invention is not restricted to any one of the given examples. Brown does not want to be limited to such details. Other obvious equivalent alternative polymers would have been an obvious modification.

Applicant's own disclosure admits that the details of the EAP are well known. Such details have already been provided by the prior art. The details of the electroactive polymer actuator are well known as admitted by applicant's disclosure in the paragraph beginning on the bottom of page 5 and continuing to page 6. "Additional information regarding the construction of such actuators, their design considerations and the materials and components that may be deployed therein can be found, for example, in U.S. Pat. No. 6,249,076..." The noted prior art patent 6,249,076 is Madden which teaches the details of the electroactive polymer actuator including a counter electrode and an electrolyte-containing region.

Both Brown and applicant's invention are not limited to the details of the EAP. Such details are provided by the prior art such as Madden. As admitted by applicant, it would have been obvious to one of ordinary skill to modify Brown to use any conventional EAP such as that

taught by Madden as further taught by applicant as an obvious equivalent alternative EAP for performing the same function.

The Brown device is for applying compressive forces to parts of the body to stimulate blood flow. The Brown device is a stocking that is capable of being placed on a portion of the body and then having stimulus applied thereto to stimulate blood flow (column 1, lines 10-16). Brown teaches that prior art stocking merely constricts the musculature of the lower extremity but does not mimic the pulsatile milking action of the leg muscles upon the veins which enhance venous blood flow back to the heart (column 1, lines 54-58). "There is need to provide a sequential application of compressive forces for squeezing or constricting the muscles thereof to prevent stasis of blood with resultant thrombus formation in the leg veins and pulmonary emboli associated therewith" (column 2, lines 37-41). Clearly Brown's device is for synchronized compressions of the extremities to help blood flow back to the heart in patients that have compromised circulatory systems.

The Shabty device is also for applying compressive forces to parts of the body to stimulate blood flow. The Shabty device is a wrap that is placed on a portion of the body in segments including the ankle, calf, thigh, and buttocks sections. Tissue compression is applied to each component sequentially (paragraph 13). Shabty also teaches the apparatus producing the tissue compression to provide augmentation may be applied uniquely on every other heart beat, every second beat, or every third beat, depending on which sequence produces the most augmentation (paragraph 14). Clearly Shabty already teaches the advantage of synchronizing the compressive forces on the treatment portion of the body and takes it a step further by

synchronizing the compressive forces with the heartbeat to improve blood flow back to the heart depending on which sequence produces the most augmentation.

Hegde is also cited to teach using EAP for the treatment of enhancing blood flow back to the heart when synchronized with the heartbeat. Hedge teaches, “FIG. 62 illustrates a comparison of arterial pressure and a corresponding EKG readout when an embodiment of an EAP actuated vascular assist system is providing augmentation in a counterpulsation manner” (paragraph 244, lines 6-10). “In order to actuate the EAP elements to provide counterpulsation the pump and pacing controller 415 calculates the Q-T interval for the heart rate and triggers at the appropriate moment based on the response time of the EAP actuated system being used” (paragraph 247, lines 4-9). Therefore Hegde that it is well known to use an EAP device to provide a counterpulsation apparatus for exerting a compressive force on a treatment portion of the user’s body in synchrony with the heart beat of the user.

It would have been obvious to one of ordinary skill in the art to modify Brown and use the details of the EAP as taught by Madden as an obvious equivalent alternative means for doing the same thing as further suggested by applicant’s admission and to use the device in synchrony with the heart beat as taught by Shabty to provide the added benefit of synchronizing compressions with the heart beat to augment blood circulation by timing it with the heart to help with the return of blood flow back to the heart. Hegde is also provided to teach that it is well known to use an EAP device in counterpulsation to augment blood flow back to the heart timed with the heart beat.

*Double Patenting*

Claims 1-14,16,17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/373,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim identical subject matter.

Regarding claim 1, the "compressor" 102 of claim 1 of the copending claims (hereon referenced as "reference B") is defined to comprise receiver 108 of claim 6 that covers the exterior treatment portion of the user's body and therefore comprehends the claims. This "covering member" is claimed to have an electroactive polymer (EAP) actuator coupled to it. Due to the fact that Claim 2 of reference B states that an electrical driver is operably connected to the EAP actuator, the EAP actuator is operably connected to the covering member.

Regarding claims 3,5 see claims 8,10 of reference B.

Regarding claim 6, the computing device of claim 5 is said to be selected from a variety of computing devices, as well as a dedicated special-purpose electronic control device. This "controller" is claimed to provide a drive signal to actuate the EAP actuator.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 15,18-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/373,940 in view of Brown and Shabty et al.

Regarding claims 15,18-20,25 the copending claims lack a covering member that comprises a fabric garment. Brown 111 discloses a system comprising a garment-covering

member 10 coupled to a plurality of polymer strips 120 that contract upon the delivery of an electrical stimulus (col. 4 lines 26-42) and thus constitute a plurality of electroactive polymer (EAP) actuators. The covering member is further said to be made of an elastomeric, or flexible material (col. 5 lines 35-40). It would have been obvious to one of ordinary skill at the time the invention was made to provide the apparatus of the copending claims with a fabric garment material to facilitate the identical claimed function to an exterior portion of a user's body.

Regarding claim 21, the actuators of Brown are further said to be woven into the covering member (col. 5 lines 35-36).

Regarding claims 22-24, the copending claims lack incorporation of actuators into a garment covering member. The actuators are said to be incorporated into the covering member of Brown by weaving it into the covering material, placing them in pockets, or attaching them directly to it (col. 5 lines 32-35). A pocket constitutes multiple layers of fabric. Although the reference does not explicitly state that the actuators are stitched or glued into the covering member, it would have been obvious to provide incorporate the actuators of the copending claims by an alternate method of incorporation since it would result in an identical objective.

Regarding claims 26,27, the Brown, 111 reference lacks a heart beat sensor. Shabty et al. discloses a counterpulsation device that comprises an EKG sensor (paragraph 52), a device that measures the sinus rhythm, or electrical conductance of the head. Shabty et al teaches the advantage of timing the limb compression with the heart rate to increase the affects of blood flow return. Thus, the device provides a drive signal based on the head senor signal. It would have been obvious to one of ordinary skill at the time the invention was made to provide the counterpulsation device copending claims in view Brown, 111 with a head rate sensor as taught

by Shabty et al in order to sense the sinus rhythm of the head and to cause simultaneous compression.

Regarding claims 28,29 the copending claims in view of Brown, 111 lacks a sensor for a biological characteristic indicative of an efficaciousness of the counterpulsation pressure. The counterpulsation device of Shabty et al comprises an EKG 100 and a pulse oximetry measurement system 102 to obtain the user's blood pressure and head rate. A plethysmograph is included (paragraph 52) to determine the circulatory capacity, or blood flow, of a limb. The timing of the inflation and deflation of the covering member is coordinated with the patient's natural blood flow (paragraph 62). In other words, a drive signal is provided by a controller based on the biological sensor signal received. It would have been obvious to one of ordinary skill at the time the invention was made to provide the device of the copending claims in view of Brown, 111 with the aforementioned sensor for sensing a biological characteristic as taught by Shabty et al in order to provide a means to obtain a user's vital information and to apply appropriate treatment.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Brown doesn't teach the details of the claimed actuator. Brown isn't restricted to any specific type of EAP actuator. Any conventional EAP actuator would work. Applicant admits the EAP of the instant invention is well known. Brown teaches the convention of using the EAP actuator for compressing an exterior treatment portion of the user's



body the details of such are taught by Madden and applicant's admission and are an obvious equivalent alternative means for doing the same thing.

Applicant also argues that the cuffs of Shabty are not the type required by the instant claims and not controlled by electroactive polymers. Shabty is not cited to teach the conventional EAP device. Applicant's admission and Madden teach the details of the EAP device. Shabty is merely cited to teach that it is well known in the art of applying compressive forces to the external portion of the body for augmenting blood flow back to the heart to time the compressions with the heartbeat so that blood flowing back to the heart is flowing with the natural flow of blood under the actions of the heart. If the timing of the compressions occurred while the heart is trying to pump blood down the extremities the compressive forces on the blood would be opposed the blood flow coming from the heart. The action would be counterproductive. That is why Shabty times the compression with the heart beat so that the blood being compressed and forced back to the heart actually flows with the natural blood flow of the heart. Hegde also teaches this convention of counterpulsation and even uses an EAP device to do it.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

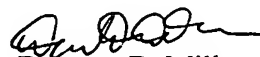
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson, can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7 August 2006

  
Danton DeMille  
Primary Examiner  
Art Unit 3764